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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. CIBT-P03-031 7778 09/827,110 04/05/2001 Elizabeth A. Wang EXAMINER 01/10/2006 28120 7590 TELLER, ROY R FISH & NEAVE IP GROUP **ROPES & GRAY LLP** PAPER NUMBER ART UNIT ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624 1654

DATE MAILED: 01/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
Office Action Summary	09/827,110	WANG, ELIZABETH A.
	Examiner	Art Unit
	Roy Teller	1654
The MAILING DATE of this communication Period for Reply	appears on the cover sheet with t	he correspondence address
A SHORTENED STATUTORY PERIOD FOR RE WHICHEVER IS LONGER, FROM THE MAILING - Extensions of time may be available under the provisions of 37 CFF after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period for reply within the set or extended period for reply will, by state Any reply received by the Office later than three months after the mearned patent term adjustment. See 37 CFR 1.704(b).	G DATE OF THIS COMMUNICAT R 1.136(a). In no event, however, may a reply riod will apply and will expire SIX (6) MONTHS atute, cause the application to become ABAND	TION. be timely filed from the mailing date of this communication. DONED (35 U.S.C. § 133).
Status		
1) Responsive to communication(s) filed on 20	0 October 2005.	
	This action is non-final.	
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is		
closed in accordance with the practice unde	er <i>Ex par</i> te Quayle, 1935 C.D. 11	1, 453 O.G. 213.
Disposition of Claims		
4)⊠ Claim(s) 63,65-68 and 70-75 is/are pending in the application.		
4a) Of the above claim(s) is/are withdrawn from consideration.		
5) Claim(s) is/are allowed.		
6)⊠ Claim(s) <u>63,65-68 and 70-75</u> is/are rejected.		
7) Claim(s) is/are objected to.		
8) Claim(s) are subject to restriction an	d/or election requirement.	
Application Papers		
9)☐ The specification is objected to by the Exam	niner.	
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.		
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).		
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).		
11)☐ The oath or declaration is objected to by the	Examiner. Note the attached Of	ffice Action or form PTO-152.
Priority under 35 U.S.C. § 119		
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:		
1. Certified copies of the priority documents have been received.		
2. Certified copies of the priority documents have been received in Application No		
3. Copies of the certified copies of the priority documents have been received in this National Stage		
application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.		
See the attached detailed Office action for a	ist of the certified copies not rec	eiveu.
Attachment(s)	_	
 Notice of References Cited (PTO-892) D Notice of Draftsperson's Patent Drawing Review (PTO-948) 	4) Interview Sumr Paper No(s)/Ma	mary (PTO-413) ail Date
 Notice of Draitsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/Paper No(s)/Mail Date 	The state of the s	mal Patent Application (PTO-152)
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DETAILED ACTION

This office action is in response to the action, received 10/20/05. Claims 63, 65-68, and 70-75 are pending.

Claim Rejections - 35 USC § 103

Claims 63, 65-68 and 70-75 are rejected under 35 U.S.C. 103 (a) as being unpatentable by Ingham (USPN 5,844,079) in view of Tabin (USPN 6,884,775).

The claimed invention is drawn to a preparation comprising a sonic hedgehog polypeptide sequence in which the polypeptide is formulated for topical application, and which polypeptide is formulated on a sponge, bandage, dressing, or film.

Ingham et al. teaches topical preparations comprising sonic hedgehog polypeptides encoded by hedgehog related genes, see e.g., for example, column 3. Ingham teaches the Shh polypeptide can comprise a fragment of at least 50, 100 or 150 amino acids in length within the N-terminal half thereof, see, e.g., for example, column 3. In addition, Ingham discloses hedgehog polypeptides which include Shh sequences corresponding approximately to the natural proteolytic fragments of the hedgehog proteins, such as from about Cys-24 through Glu-188, or from about Asn-189 through Ala-475 of the human Shh protein, or analogous fragments thereto, see, e.g., for example, column 3. Ingham discloses methods of introduction of exogenous

hedgehog polypeptides at the site of treatment include hydrogels that can be used to form an implant such as within a gauze for sustained release at a particular target site, see e.g., for example, column 52, lines 42-64. Ingham does not teach the use of bandages or dressings.

Page 3

Tabin et al. teaches hedgehog polypeptides, which encompass preparations of hedgehog proteins and peptidyl fragments, can be used to make plasters, bandages, dressings, gauze pads and the like, see, i.e., for example, columns 53-54, and column 57, lines 8-14.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Ingham with the beneficial teachings of Tobin, because Tobin discloses preparations of hedgehog polypeptides can be used to make plasters, bandages, dressings, gauze pads and the like.

Conclusion

All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is 571-272-0971. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 09/827,110

Art Unit: 1654

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RT 1654

1/3/06

RT

JON WEBER

SUPERVISORY PATENT EXAMINER

Page 4